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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,871	03/18/2004	Philip Russel James Smith	66347-104	5458
68804	7590	06/26/2009		
JOHN P. DE LUCA 17420 RYEFIELD CT. DICKERSON, MD 20842			EXAMINER RAMDHIANE, BOBBY	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 06/26/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/802,871

Applicant(s)

SMITH ET AL.

Examiner

BOBBY RAMDHANIE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection are necessitated by Applicants' amendments to the claims.
2. Applicant's arguments filed 04/15/2009 in regards to the Day reference have been fully considered but they are not persuasive. The following reasons are why:
3. Applicant argues that "the deformable or flexible formation at the end of the claimed tube allows the tube to fit through the bore, pass beyond the bottom opening thereof and snap fit to engage the bottom of the plate" and that "this is not possible" in the Day reference (Please see Remarks filed on 04/15/2009; Page 9)." This statement is unpersuasive because the statement lacks any factual evidence.
4. Applicant also argues, "In each case, the bottom of the tube is bigger than the body of the tube so that the tube can be snap fit into the plate (Please see Remarks filed on 04/15/2009; Page 9)." This is unpersuasive because this is not recited in the claim language as such. What is recited is that a connector portion is located "at a second end of the tube." This scope of the invention recited in the claim language is far beyond the scope of the invention that is being argued.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1 & 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day in view of Wyszynski et al (US20040261219) and in further view of Verwohlt et al (US5514343).

8. Applicant's claims are toward "a combination" or "a tube."

9. Regarding Claims 1 & 6-14, Day discloses a tube for storing micro-litre volumes, the tube having first and second ends, the tube being open at the first end and a second closed end, adapted at the second end of the tube for to engage engaging the bottom surface of the multi-well plate, the tube comprising: A). A body portion of substantially square cross section (See Figure 2); B). A shoulder portion near said one end of the body portion and providing the open end of the tube, the cross section of the shoulder

portion being greater than that of the body portion (See Figures 1, 13, & 14); and C). A deformable formation providing a connector portion at the second end of the tube (See Figure 2 Item 22).

10. Day does not disclose that the tube has the intended use of explicitly being placed "in combination" with a multiwell plate. Day does however disclose the problem of the growing need to operate on and store increasingly large numbers of samples AND a typical example of operating and storing these number of samples is done via cluster tubes which are explicitly disclosed to be used with a heavy duty rack in a standard microplate format (The Examiner interprets this limitation as a multi-well plate).

11. Wynschenk et al discloses a multi-well plate having a top surface and a bottom surface and through bores having a substantially square cross section parallel to the top and bottom surfaces extending through the plate from the top surface to said bottom surface, said through bores for receiving one tube in a corresponding one of the through bores in said multi-well plate (See Figures).

12. Verwohlt et al discloses "in combination," A). A tube for storing micro-litre volumes and B). A multi-well plate having a top surface and a bottom surface and through bores having a substantially square cross section parallel to the top and bottom surfaces extending through the plate from the top surface to said bottom surface (See Figure 1), said through bores for receiving one tube in a corresponding one of the through bores in said multi-well plate (See Figure 1), the tube having first and second ends, the tube being open at the first end and a second closed end (See Figure 4); C). The tube comprising: 1). A body portion of substantially square cross section

corresponding to the cross section of the through bores (See Column 2 lines 12-28); 2). A shoulder portion near said one end of the body portion and providing the open end of the tube, the cross section of the shoulder portion being greater than that of the body portion (See Figure 4 part of the shoulder portion is indeed larger than the body portion – Item 22).

13. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the operation, use, and storage of the tubes of Day and place the tubes of Day into the multi-well plate of Wynschenk et al so that the deformable formation having a cross section larger than the cross section of the bores providing a connector portion at the second end of the tube, said formation being deformable to fit through the through bore and to extend through the bottom surface to form a snap fit engagement with said bottom surface of the multi-well plate, because Verwohlt et al has already shown that tubes with rectangular sidewalls and multi-well plates with rectangular through bores can be placed together via a snap-fit engagement and according to Day, the snap-fit engagement (Item 22) on the rim of the cap around the outer circumference aids in the removal and placement of the cap (See [0078]).

14. Additional Disclosures Included: Claim 6: Wherein the body and shoulder portions are formed separately from the snap fit connector portion (See Day; [0013-0019] & (See [0026-0028] & See Figure 2); Claim 7: Wherein the snap fit connector portion has a dot code on it (See Day; [0026-0028] & [0104]); Claim 8: Wherein the body and shoulder portions are formed from a translucent or transparent material (See [0074]); Claim 9: The combination according to claim 8, further comprising a spigot at

the interface between the body portion and the formation snap fit connector portion (See Day [0096] & See Figures); Claim 10: Wherein the body portion and snap fit connector portion are co-moulded (See [0076] & Claim 22; The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)); Claim 11: In combination a tube for storing fluid and a multi-well plate having a top surface and a bottom surface and through bores having a substantially square cross section parallel to the top and bottom surfaces extending through the plate from the top surface to said bottom surface, said through bores for receiving one tube in a corresponding one of the through bores in said multi-well plate, the tube having first open end and a second closed end, the closed end for engaging the bottom surface of the multi-well plate, the tube comprising: a body portion of substantially square cross section corresponding to the cross section of the through bores; a shoulder portion near said first end of the body portion and providing the open end of the tube, the cross section of the shoulder portion being greater than that of the body portion; and a deformable flared portion at the second end of the tube having a cross section greater than the through bores and being deformable to fit through the through bore and to extend through the bottom surface to form a snap fit engagement with the bottom surface of the multi-well plate said flared portion having an identification code provided thereon (See Rejections above and Day Figures 13, 14, Figure 2 Item 22, See Day [0004], [0027-0033]; [0104]); Claim 12: The combination

according to claim 11, wherein the connector and body portions are formed separately from different materials (See [0074] & [0094]); Claims 13: The tube for storing fluid for use with a multi-well plate having a bottom surface and through bores having a substantially square cross section extending through the plate to said bottom surface, said through bores for receiving one tube in a corresponding one of the through bores in said multi-well plate, the tube having a first open end and a second closed end the closed end of the tube for engaging the bottom surface of the multi-well plate, the tube comprising: a body portion having a substantially square cross section corresponding to the cross section of the through bores; a shoulder portion near said first end of the body portion above the square cross section, the cross section of the shoulder portion being greater than that of the body portion; and a deformable flared connector portion at the second end of the tube having a cross section greater than the through bores and being deformable to fit through the through bore and to extend through the bottom surface to form a snap fit engagement with the bottom surface of the multi-well plate, said flared connector portion having an identification code provided thereon (See Rejections above); Claim 14: A tube for storing fluid comprising: a body portion having a substantially square cross section, an open upper end and a closed lower end; a shoulder portion spaced below the upper end, the cross section of the body portion above the shoulder portion being greater than that of the body portion; and a deformable flared connector portion at the lower end of the tube having a cross section greater than the body portion and being deformable, said flared connector portion having an identification code provided thereon (See Rejections above).

15. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day in view of Wyszchen et al (USD466219) and Verwohlt et al (US5514343) and in further view of Helger et al and Stanchfield et al.

16. Applicants' claims are toward "a combination."

17. Regarding Claims 2-5, the combination of Day, Wyszchen et al, and Verwohlt et al disclose the "in combination" of claim 1, except for 1). Further comprising a closure member disposed to close the open end; 2). Wherein the closure member comprises a foil cap; 3). Wherein the closure member is a self-sealing member; and 4). Wherein the self-sealing closure member is a split septum. All three references do however disclose their use with tubes that essentially will hold some type of fluid.

18. Helger et al teaches a closure member comprising a foil cap (Column 2 lines 30-50) and Stanchfield et al teaches a closure member comprising a self sealing member or split septum (Column 11 lines 25-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Day, Wyszchen et al, and Verwohlt et al, in view of Helger et al and Stanchfield et al because according to Helger et al, using a foil cap can be advantageous when the sample of interest needs to be freeze dried and must be sealed for preservation reasons, sample containers sealed with foil caps provide a very good seal, can withstand an internal pressure of 2 atm, and the foil can be removed or punctured to remove the sample at a later time (Column 4 lines 50-60 and Column 5 lines 0-5) and according to Stanchfield et al, the rubber materials are chemical resistant and are well

known for forming septa for sealing round bottom flasks and Erlenmeyer flasks and other containers commonly used by researchers (Column 11 lines 29-40).

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797